

CLAIMS

1. A medical device configured to be disposed within a body lumen, said device comprising:

5 a membrane; and
reinforcement fibers coupled to said membrane to form a composite structure therefrom.

2. The device of claim 1, further comprising a frame attached to said composite
10 structure to hold said membrane in a desired shape, said frame comprising a proximal end and a distal end.

3. The device of claim 2, further comprising an elongated member configured to transport said device to an appropriate location in said body lumen.

15 4. The device of claim 3, wherein said elongated member comprises a guide wire attached to at least one of said frame or said composite structure.

5. The device of claim 4, wherein said proximal end of said frame is remote from said
20 membrane unit.

6. The device of claim 5, further comprising pulling fibers connecting said proximal end of said frame to said guide wire to enable said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body
25 lumen.

7. The device of claim 4, wherein said distal end of said frame is adjacent said membrane unit, and wherein said reinforcement fibers are connected between said distal end of said frame and said guide wire for enabling said device to be extracted from a
30 delivery sheath by pushing on said guide wire to impose a pulling force on said composite structure in order to introduce said device into said body lumen.

8. The device of claim 4, further comprising a plurality of slide rings, each of said slide rings connected to opposing ends of said device such that said slide rings are responsive to displacement forces imparted thereto by said guide wire.

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9. The device of claim 8, wherein said reinforcement fibers are directly attached to one of said slide rings and said distal end of said frame.

10. The device of claim 9, further comprising pulling fibers connecting said proximal end of said frame to said guide wire for enabling said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body lumen.

11. The device of claim 9, wherein said proximal section of said frame is tapered to facilitate retraction of said frame into a sheath.

12. The device of claim 4, further comprising a pressure sensing tip coupled to said guide wire.

13. The device of claim 4, wherein said frame is configured to allow said guide wire to move freely in axial, radial, tangential and rotational directions within said frame when said frame is in an expanded state without influencing the position and shape of said device.

14. The device of claim 1, wherein said device is configured as one filter of a double filter system.

15. The device of claim 4, wherein said frame has elongated struts that define attachment points at said proximal end to facilitate connection of said frame to said guide wire.

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16. The device of claim 15, further comprising pulling fibers connected to said attachment points by means of attachment holes disposed therein.

17. The device of claim 15, further comprising pulling fibers connected to said attachment points by gluing or welding.

18. The device of claim 4, further comprising a hollow tube advanceable into a region at least partially enclosed by said composite structure when said composite structure is in an open state.

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19. The device of claim 18, wherein said guide wire is configured to fit within said hollow tube.

20. The device of claim 18, wherein said tube is configured to perform at least one of a suction, flushing, inspection, measuring, clot-breaking, and retrieval device introduction functions while said tube is advanced into said at least partially enclosed region.

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21. The device of claim 20, wherein said hollow tube is dimensioned to serve as a removal sheath for said device.

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22. The device of claim 3, wherein said elongated member is configured to be detached from said frame.

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23. The device of claim 22, further comprising:

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a slide ring coupled to said device; and

a hollow tube disposed within said slide ring, wherein said hollow tube comprises a longitudinally split distal end movably responsive to said elongated member such that when said elongated member is adjacent said longitudinally split distal end, said longitudinally split distal end expands, thereby affixing said hollow tube to said slide ring, and when said elongated member is removed from said longitudinally split distal end, said

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longitudinally split distal end contracts, thereby allowing said hollow tube to be removed from said slide ring such that said device remains in said body lumen even after said hollow tube is removed.

5 24. The device of claim 2, wherein said reinforcement fibers are attached to said frame.

25. The device of claim 2, wherein said reinforcement fibers are attached to said frame by connections that are configured to form hinges in said frame.

10 26. The device of claim 2, wherein said frame is constructed to collapse and expand said composite structure.

27. The device of claim 1, wherein said membrane defines a plurality of holes therein to allow passage of a body fluid, while preventing passage of particles above a certain
15 size.

28. The device of claim 27, wherein each of said plurality of holes is up to approximately 100 microns in diameter.

20 29. The device of claim 27, wherein said plurality of holes are arranged in a substantially repeating pattern in said membrane.

30. The device of claim 1, wherein the material making up said reinforcement fibers have a tensile stress and modulus of elasticity greater than the material making up said
25 membrane.

31. The device of claim 1, wherein said reinforcement fibers comprise a plurality different fiber types, including fibers for shape control combined with fibers with high tensile strength.

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32. The device of claim 1, wherein said reinforcement fibers are monofilament or multi-filament fibers.

33. The device of claim 1, wherein said reinforcement fibers are discontinuous and
5 dispersed throughout said membrane.

34. The device of claim 1, wherein said reinforcement fibers are coated with a polymer to enhance adhesion between said reinforcement fibers and said membrane.

10 35. The device of claim 1, wherein said reinforcement fibers are glued to said membrane.

36. The device of claim 1, wherein the material making up said membrane comprises a polymer, an organic tissue, or a tissue of human or animal origin.
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37. The device of claim 1, wherein the material making up said reinforcement fiber is selected from the group consisting of carbon, glass, ceramics, metals, metal alloys, polymers and combinations thereof.

20 38. The device of claim 1, further comprising a biocompatible material disposed on at least a portion of said device.

39. The device of claim 38, wherein said biocompatible material prevents the adherence of emboli or platelets to said device.
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40. The device of claim 38, wherein said biocompatible material releases a drug into said body lumen.

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41. The device of claim 1, wherein said composite structure is a filter that is expandable into an expanded state, said filter comprising a substantially closed distal end and an open proximal end such that said filter tapers from said proximal end to said distal end.

42. The device of claim 41, further comprising a reservoir in said filter that extends from said distal end, said reservoir defining a debris storage space.

43. The device of claim 2, wherein said frame allows said device to expand until a predetermined expanded size limit is reached.

44. The device of claim 43, wherein said reinforcement fibers are oriented in such a way as to give said composite structure a shape that depends, within predetermined limits, on the pressure difference across said composite structure.

45. The device of claim 1, wherein said device comprises a removable temporary stent, a dilator, a reamer, an arterial occlusion device, a graft housing, a valve, a surgical clip or a delivery platform for drugs, radiation or gene therapy.

46. The device of claim 1, wherein said membrane is substantially free of holes such that said membrane is substantially non-porous.

47. The device of claim 46, wherein said device comprises a skin for grafts, a stent, a catheter component, an inflatable member, a balloon pump, a retrieval bag or a body tissue replacement.

48. A medical device configured to be disposed within a body lumen, said device comprising:

a composite structure comprising:

a membrane; and

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reinforcement fibers coupled to said membrane to form said composite structure;
a frame attached to said reinforcement fibers; and
an elongated member attached to at least one of said frame or said composite
5 structure to facilitate movement of said composite structure into said body lumen.

49. The device of claim 48, wherein said frame is expandable such that in a first state, said frame and said composite structure define a first size profile that is configured to be transported by said elongated member to a desired location within said body lumen, while
10 in a second state, said frame and said composite structure define a second size profile that is configured to engage said body lumen.

50. The device of claim 48, wherein said composite structure defines a plurality of holes in said membrane.

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51. The device of claim 48, further comprising:

a first ring slidably disposed on said elongated member and coupled to a distal end of said composite structure;

a second ring slidably disposed on said elongated member and coupled to a
20 proximal end of said frame; and

a plurality of stops affixed to said guide wire such that upon contact between one of said stops and one of said first or second rings due to movement of said elongated member, said device moves either into or out of said body lumen.

25 52. The device of claim 48, wherein said elongated member comprises a guide wire.

53. A vascular filter assembly comprising:

a filter comprising:

a membrane defining a plurality of holes therein; and

30 reinforcement fibers coupled to said membrane to form a composite structure;

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an expandable frame attached to said reinforcement fibers; and
a guide wire attached to at least one of said frame or said filter to facilitate movement of said assembly into said body lumen.

5 54. The vascular filter of claim 53, wherein said guide wire is attached to each of said filter and frame.

55. A medical device configured to be disposed within a body lumen, said device comprising:

10 a composite structure comprising:

a membrane; and

first fibers coupled to said membrane to form said composite structure;

a frame attached to said composite structure;

second fibers coupled to said frame;

15 a guide wire coupled to said frame and said composite structure through said first and second fibers such that said first and second fibers and said guide wire are configured to move said composite structure and said frame.

56. The device of claim 55, wherein said first fibers comprise reinforcement fibers.

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57. The device of claim 56, wherein said frame is attached to said composite structure through said reinforcement fibers.

58. The device of claim 55, wherein the material making up said first and second fibers
25 is the same.

59. The device of claim 55, wherein said reinforcement fibers are discontinuous and dispersed throughout said membrane.

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60. A medical device configured to be disposed within a body lumen, said device comprising:

a non-filter membrane; and

reinforcement fibers coupled to said membrane to form a composite structure
5 therefrom.

61. A method of fabricating a medical device configured to be disposed within a body lumen, said method comprising:

providing a removable mold in substantially a shape of said device;

10 covering said mold with membrane material;

placing fibers in contact with said membrane material;

covering said fibers with additional membrane material to form a composite structure; and

removing said mold.

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62. The method of claim 61, comprising the additional step of covering said mold with an intermediate material that is easily separated from said membrane material prior to said step of covering said mold with said membrane material.

20 63. The method of claim 62, comprising the additional step of removing said intermediate material from said membrane.

64. The method of claim 61, wherein said step of removing the mold is by melting, dissolving, or deforming the mold.

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65. The method of claim 64, wherein the mold is made of a material that dissolves in a liquid.

66. The method of claim 64, wherein the mold is made of a sheath filled with fine solid
30 grains and then vacuum sealed.

67. The method of claim 61, wherein the mold is an expandable or inflatable structure.

68. The method of claim 61, further comprising coating said composite structure with an additional material having a property not possessed by the materials making up said
5 composite structure.

69. The method of claim 61, comprising the additional step of connecting a frame to said composite structure.

10 70. The method of claim 69, wherein said step of connecting said frame to said composite structure comprises attaching said reinforcement fibers disposed in said composite structure to said frame.

71. The method of claim 69, wherein said frame is expandable.

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72. The method of claim 70, comprising the additional step of connecting a guide wire to at least one of said frame or composite structure.

73. The method of claim 61, comprising the additional step of forming a plurality of
20 holes in said membrane.

74. The method of claim 73, wherein said step of forming holes is by laser drilling.